

REMARKS

Amendments to the Claims

Claims 53, 69, 86, 87 and 88 have been amended to recite a “pharmaceutical composition,” support for which can be found in the specification as originally filed at least in paragraph [0132] *et seq.*

Claims 53, 69, 72 and 86 to 88 have been amended to recite a “pharmaceutically acceptable carrier or diluent,” basis for which can be found at least in paragraphs [0020] and [0128].

For the foregoing reasons Applicants respectfully submit that the amended claims are fully supported by the specification as originally filed and do not include new matter.

The Status of Claims 56 and 57

Applicant thanks the Examiner for drawing attention to the status identifier set forth for claim 57 in a previous response. Applicant has reviewed the file and noted the Examiner apparently intended to comment upon claim 56, not claim 57. In any event, presently, both claims are marked "Previously Presented" as that correctly characterizes their status.

Unity of Invention

In response to the Restriction Requirement, Applicant provisionally elects, with traverse, human immunodeficiency virus as the species of pathogenic organism to which the recited target antigen relates (claim 83). The elected species reads on claims 53 to 67, 73 to 83, and 86 to 88.

Applicant traverses the position taken by the Patent and Trademark Office that the claims are directed to more than one species of generic invention and that they lack unity as they do not make a contribution over the prior art in view of Pryjma *et al.*, (1994, *Infect. Immun.*, **62**(5): 191961-1967). The Pryjma reference fails to teach or fairly suggest the pharmaceutical composition for modulating an immune response set for in the present claims, and therefore fails to teach the special technical feature uniting the claims. Indeed, the human monocyte suspensions disclosed by Pryjma *et al* were incubated in either RPMI 1640

medium or complete medium containing fetal calf serum (FCS) (see page 1962, left column, first and second paragraphs). Applicant submits that a skilled artisan would understand that FCS proteins cause adverse immune responses and should be avoided in cell therapy applications. See, for example, Spees *et al.*, 2004, *Molecular Therapy* 9(5):747-756; Mackensen *et al.*, 2000, *Cancer Immunol Immunother* 49:152-156; and Selvaggi *et al.*, 1997, *Blood* 89(3): 776 to 779, copies of which are *enclosed* for the Examiner's consideration. It is apparent, therefore, that the human monocyte suspensions disclosed in the Pryjma reference would be unsuitable for administration to human subjects.

Applicant further submits the Pryjma reference discloses a study on the use of extracellular bacteria as a phagocytic stimulus to determine whether phagocytosis would have any impact on monocyte performance as antigen presenting cells. The results of that study show that after monocytes ingest bacteria, they are defective as antigen presenting cells with altered co-stimulatory functions. In addition, that study indicates that antigen-driven T-cell proliferation and interferon gamma production were much lower when monocytes with bacteria were used as antigen presenting cells (see, page 1965, left column, second paragraph). The authors concluded that phagocytosis of bacteria by monocytes affects their antigen-presenting and accessory functions presumably because of changes in the expression of molecules essential for monocyte-T-cell interactions and reduction of their viability.

Applicant submits that from the foregoing, it is clear that the Pryjma reference is neither concerned with vaccinating subjects with uncultured, non-activated antigen presenting cells that have been pulsed with a target antigen of a pathogenic organism, nor would the study set forth in that reference suggest such treatment to the skill artisan. As such, the reference is ineffective to destroy the unity of invention of the present claims.

In view of the foregoing, Applicant respectfully requests withdrawal of the lack of unity holding and the examination of all claims.

Conclusion


Applicants believe that this response is a complete reply to the restriction/election of species requirement issued on March 11, 2010. A first office action on the merits is awaited. It is respectfully submitted that the application is in condition for examination, and an early action on the merits is courteously requested. In the event the Examiner requires any further information, or would like to schedule an interview to advance prosecution in this application, the Examiner is encouraged to contact Applicants' undersigned representatives.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-2283. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

Respectfully submitted,

Date: September 13, 2009

Perkins Coie LLP
607 14th St., NW
Suite 800
Washington, DC 20005
Telephone: 202.628 6600
Facsimile: 202.434.1690


Joseph W. Ricigliano (Reg. No. 48,511)
Paul M. Booth (Reg. No. 40,244)
Attorneys for Applicant

Customer No. 91106